REMARKS

Reconsideration of this application is requested in view of the amendments to the claims and the remarks presented herein.

The claims in the application are claims 1 and 3 to 11, all other claims having been cancelled.

Claims 1 to 11 were rejected under 35 USC 112 as being indefinite in the expression "paraben esters".

Applicant respectfully traverses these grounds of rejection since the expression "paraben esters" has been replaced with "esters of p-hydroxybenzoic acid" and therefore, the claims are not indefinite.

Claims 1 to 5 and 9 were rejected under 35 USC 102 as being anticipated by the NG et al patent which, according to the Examiner, teaches a vaccine formulation in a base stock solution comprising an immunogen, pharmaceutically acceptable excipients aluminum hydroxide and a preservative wherein the preservative is a combination of methyl and ethyl esters of p-hydroxybenzoic acid and 2-phenoxyethanol which requires L-histidine as a buffer to keep the pH at 7. Claims 6, 10 and 11 were rejected under 35

USC 103 as being obvious over the NG et al patent taken in view of the Marciani patent which is cited to show the use of saponin in vaccine formulations. Claims 7 and 8 were rejected as being obvious thereover over the NG et al patent alone since it was deemed that the concentrations would be obvious to one skilled in the art.

Applicant respectfully traverses this ground of rejection since the NG et al patent does not anticipate nor render obvious Applicant's invention. The NG et al reference relates to a combination of preservatives comprising methyl and propyl parabens, benzyl alcohol and 2-phenoxyethanol which must use L-histidine as a buffer to keep the vaccines at a pH of 7.0. It should be noted that Applicant's compositions do not require L-histidine as a buffer to keep the pH at 7 and lacks the benzyl alcohol which is required by the reference. The terminology "consisting essentially of" has been used to exclude the presence of these two ingredients from Applicant's vaccine formulations. Applicant's compositions are not merely a combination of two compositions, each of which is taught by the prior art since the data in the application as filed on pages 9 and 10 unequivocally shows the immunogenic effect of the vaccine when used to vaccinate guinea pigs and pigs and this combination could in no way be ascertained from the NG et al reference whether taken alone or in further view of the Marciani patent.which only teaches that saponin can have an antimicrobial activity and can be used in vaccine formulation. It in no way overcomes the deficiencies of the NG et al patent as discussed above. Therefore, withdrawal of these grounds of rejection is requested.

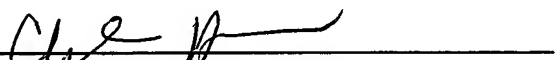
Claims 1, 5 and 7 to 9 were rejected as being obvious over the Pillai et al reference and claims 6, 10 and 11 were rejected under 35 USC 103 as being obvious thereover taken in view of the Marciani patent. The Examiner states that the Pillai et al reference teaches vaccine formulations and base stock solutions comprising an adjuvant, an immunogen, aluminum hydroxide and a preservative, which preservative might include methyl paraben, ethyl paraben and 2-phenoxyethanol. The Examiner concedes that the reference does not teach a combination of at least two parabens and 2-phenoxyethanol but deems that it would be obvious to combine the individual ingredients.

Applicant respectfully traverses these grounds of rejection since it is deemed that the Pillai et al reference, taken alone or in combination with the secondary references, would not in any way suggest Applicant's novel compositions. The Pillai et al reference relates to interleukin containing vaccine compositions comprising a mixture of antigen and an adjuvant amount of an interleukin absorbed onto a mineral suspension and a preservative. The mineral is preferably alum and on page 3, lines 21 to 24, it is indicated that the composition may comprise any pharmaceutically acceptable preservative including thimerosal, phenol, m-cresol, benzyl alcohol, methyl or ethyl paraben and 2-phenoxyethanol. In claims 17, 19 and 20, it is stated that the preservative may be thimerosal, phenol, benzyl alcohol, methyl or ethyl paraben, 2-phenoxyethanol or m-cresol. There is absolutely no preservative indicated in the examples of the application and there is no indication whatsoever of any mixtures of preservatives, much less

Applicant's mixture of two esters of p-hydroxybenzoic acid and 2-phenoxyethanol. As noted above, the application clearly shows the advantage of using the combination of three preservatives in Applicant's invention which are in no way suggested by the Pillai et al reference taken alone or with the secondary references. Therefore, it neither anticipates nor renders obvious Applicant's invention and withdrawal of the same is requested.

In view of the amendments to the claims and the above remarks, it is believed that the claims clearly point out Applicant's patentable contribution and favorable reconsideration of the application is requested.

Respectfully submitted,
Muserlian, Lucas and Mercanti



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CAM:ds
Enclosures